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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,513	07/25/2001	Nicholas P. Harberd	620-157	4244
75			EXAMI	NER
NIXON & VA 8th Floor	NDERHYE P.C.		MEHTA, ASHWIN D	
1100 North Glel Arlington, VA			ART UNIT	PAPER NUMBER
Armigion, VA	22201-4714		1638	10
		•	DATE MAILED: 11/06/2003	17

Please find below and/or attached an Office communication concerning this application or proceeding.

64	,	Applicati n No.	Applicant(s)
		09/911,513	HARBERD ET AL.
	Office Action Summary	Examiner	Art Unit
		Ashwin Mehta	1638
Period fo	The MAILING DATE of this communicati n app or Reply	pears n the c ver sheet with the c	rresp ndence address
THE I - External after - If the - If NO - Failu - Any r	ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. Insions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. Period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute eply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from a Cause the application to become ARANDONE.	nely filed s will be considered timely. the mailing date of this communication.
1)⊠	Responsive to communication(s) filed on 11 J	lune 2003 and 19 December 200	2.
2a)⊠	_	is action is non-final.	-
3) <u></u> Dispositi	Since this application is in condition for allowation closed in accordance with the practice under to on of Claims	ance except for formal matters, pr	osecution as to the merits is 53 O.G. 213.
4)🖂	Claim(s) 49-59 and 61-69 is/are pending in the	e application.	
	4a) Of the above claim(s) is/are withdraw	vn from consideration.	
	Claim(s) is/are allowed.		
6)⊠	Claim(s) <u>49-59, 61-69</u> is/are rejected.		
	Claim(s) is/are objected to.		
8)[	Claim(s) are subject to restriction and/or	election requirement.	
	on Papers	. 1	
9)[] 7	he specification is objected to by the Examiner	<b>`</b>	
10)⊠ ٦	he drawing(s) filed on <u>19 December 2002</u> is/ar	e: a)⊠ accepted or b)⊡ objected to	by the Examiner.
	Applicant may not request that any objection to the		
11)[] 7	he proposed drawing correction filed on	is: a) ☐ approved b) ☐ disapproved	
	If approved, corrected drawings are required in rep	ly to this Office action.	
12)∐ T	he oath or declaration is objected to by the Exa	aminer.	
Priority u	nder 35 U.S.C. §§ 119 and 120		
13)🖂	Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a)	-(d) or (f).
	☑ All b) ☐ Some * c) ☐ None of:		., .,
	1. Certified copies of the priority documents	have been received.	
	2. Certified copies of the priority documents	have been received in Application	n No. <i>09/177,853</i> .
	3. Copies of the certified copies of the priori application from the International Burdee the attached detailed Office action for a list of	ty documents have been received	d in this National Stage
	knowledgment is made of a claim for domestic		
a) 15)⊠ A	☐ The translation of the foreign language provious the control of the translation of the foreign language provides the control of the translation	visional application has been rece	ived.
ttachment(			
2) 🔲 Notice	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449) Paper No(s) <u>13</u>	5) Notice of Informal Pa	PTO-413) Paper No(s) stent Application (PTO-152)
Patent and Tra OL-326 (Re	± • ± · ·	ion Summary	Part of Paper No. 14

Art Unit: 1638

## **DETAILED ACTION**

- 1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 2. The objection to the oath/declaration is withdrawn, upon further consideration.
- 3. The objection to the specification for failing to comply with 37 CFR 1.821-1.825 is withdrawn, in light of insertion of sequence identifiers in the relevant locations.
- 4. The objections to claims 50, 55-58, and 60-68 are withdrawn, in light of the claim amendments.
- 5. The rejection of claims 49-69 under the judicially created doctrine of obviousness-type double patenting is withdrawn, in light of the terminal disclaimer submitted 19 December 2002. The terminal disclaimer was found to be in proper form and was recorded.
- 6. The rejections of claims 52, 54, and 59-67 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, are withdrawn in light of the claim amendments or further consideration.

Claim Rejections - 35 USC § 112

Art Unit: 1638

7. Claims 50, 53, 55-58, 68, and 69 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed June 19, 2002 under item 6. Applicants traverse the rejection in the paper submitted December 19, 2002. Applicants' arguments were fully considered but were not found persuasive.

Regarding the indefinite issue of the term "antagonized" in claims 50 and 53, Applicants argue that it takes its normal meaning as understood in the chemical and biological fields, and argue that an antagonist of an inhibition of growth of a plant opposes the activity (response, paragraph bridging pages 17-18). However, the relevant art does use the term "antagonist" when referring to the affect that GA has on the inhibition of growth. It is also noted that the two post-filing references submitted by Applicants on June 11, 2003 (Xu et al. and Fu et al.) do not refer to GA as "antagonizing" the inhibition of plant growth caused by GAI.

Regarding the rejection of claims 59 and 69, for improper antecedent basis for the recitation, "heterologous nucleic acid according to any one of claims 49 to 54": Applicants argue that this rejection appears to be inconsistent with the granted claims in the parent case (response, page 18, 3<sup>rd</sup> full paragraph). However, patented claim 7 of 6,307,126, for example, is directed to a host cell that containing the nucleic acid according to claim 1, wherein said nucleic acid is heterologous to said host cell. The rejection is not inconsistent with the patented claims.

Art Unit: 1638

8. Claims 61-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 61 is indefinite because it is dependent on cancelled claim 60. Claims 62-67 are indefinite as they depend from claim 61.

9. Claims 49, 52-59, and 61-69 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed June 19, 2003, under item 7. Applicants traverse the rejection in the papers submitted December 19, 2002 and June 11, 2003. Applicants' arguments were fully considered but were not found persuasive.

Although claims 61-69 are currently dependent on a cancelled claim, to expedite prosecution they remain included in this rejection assuming that Applicants intend claim 61 to be dependent on claim 59.

Applicants argue that the claims define a narrow genus by sequence, structure and function, that various alleles and mutants are described and discussed, and that homologous sequences have been found in various species (response submitted June 11, 2003, paragraph bridging pages 3-4; response submitted December 19, 2002, page 19, 1<sup>st</sup> full paragraph, page 20, 1<sup>st</sup> full paragraph to the paragraph bridging pages 20-21). Applicants argue that the claims require the presence of a particular 17 amino acid sequence, and the experiments described

Art Unit: 1638

demonstrate that the presence or absence of the defined 17 amino acid sequence is functionally significant (response submitted June 11, 2003, page 20, 1<sup>st</sup> full paragraph).

However, the specification mentions mutants that encode proteins that do not have the same activity as SEQ ID NO: 2. The alleles also do not have to have the same activity of SEQ ID NO: 2. Further, the sequences of nucleic acids encoding SEQ ID NO: 2 do not provide any information concerning the sequences of all alleles and mutants. Applicants mention that the presence of a particular 17 amino acid sequence is required. However, this limitation is not recited in claims 52-54. Further, claims 49 and 52 do not even mention any activity for the polypeptide encoded by the isolated nucleic acid. Those claims then encompass isolated nucleic acids having any function. Furthermore, the specification does not describe the amino acid sequences of any species homologs or whether these homologs were known as of the effective filing date of the instant application. Furtherstill, the hybridization conditions recited in claims 52-54 are not described in the specification. Applicants indicate that the conditions are from Peng et al. (Plant Cell, 1993, Vol. 5, pages 351-360), which is reference 5 in the application and is of record (response submitted December 19, 2002, page 18, 2<sup>nd</sup> full paragraph). However, the specification does not indicate that the references have been incorporated by reference.

Applicants also argue that the situation here is distinct from <u>Fiers</u>, that more is provided than a mere statement that the certain sequences are part of the invention (response submitted December 19, 2002, 1<sup>st</sup> full paragraph). The Examiner maintains that written description has not been met, for the reasons discussed above.

Art Unit: 1638

10. Claims 52-59 and 61-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards any isolated nucleic acid that hybridizes to the complement of a nucleic acid coding for the amino acid sequence as shown in SEQ ID NO: 2 under the hybridization conditions recited in claims 52-54, wherein the hybridizing nucleic acid can encode a product with any function, or wherein expression of the hybridizing nucleic acid in a plant results in inhibition of plant growth, the inhibition being antagonized by GA, or wherein expression in a plant complements a GAI null mutant phenotype, such phenotype being resistance to the dwarfing effect of paclobutrazol; a nucleic acid vector suitable for plant transformation, comprising said nucleic acid; a method of producing a plant, comprising incorporating said nucleic acid into a plant cell and regenerating a plant; or a method for influencing a plant characteristic, comprising said nucleic acid in a plant, wherein said nucleic acid is heterologous to the plant.

Claims 52-54 have been amended to recite particular hybridization conditions.

Applicants argue that the conditions are from Peng et al. (Plant Cell, 1993, Vol. 5, pages 351-360), which is reference 5 in the application and is of record (response submitted December 19, 2002, page 18, 2<sup>nd</sup> full paragraph). However, the specification does not indicate that the references have been incorporated by reference. The hybridization conditions are therefore

NEW MATTER and must be removed from the claims. Although claims 61-69 are currently

Art Unit: 1638

dependent on a cancelled claim, to expedite prosecution, they are included in this rejection assuming that Applicants intend claim 61 to be dependent on claim 59.

11. Claims 49-59 and 61-69 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 2 and a method of inhibiting plant growth and delaying flowering time comprising expressing SEQ ID NO: 2 in cells of a plant wherein SEQ ID NO: 2 is heterologous to the plant, and plant and bacterial host cells, does not reasonably provide enablement for isolated nucleic acids having a nucleotide sequence encoding a polypeptide that has 90% identity to SEQ ID NO: 2, or methods to influence plant growth and flowering time in any other manner, or other types of host cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record stated in the Office action mailed June 19, 2003, under item 8. Applicants traverse the rejection in the papers submitted December 19, 2002 and June 11, 2003. Applicants' arguments were fully considered but were not found persuasive.

Although claims 61-69 are currently dependent on a cancelled claim, they remain included in this rejection assuming that Applicants intend claim 61 to be dependent on claim 59.

Applicants argue that the skilled person would know how to mutate a given sequence and obtain variants, and that the disclosure guides one in obtaining a functional sequence because a functional GA-responsive domain is identified in the specification (response submitted June 11, 2003, page 4, 1<sup>st</sup> full paragraph and the paragraph bridging pages 4-5). However, the 17 amino acid sequence that makes up the GA-responsive domain represents only 3.2% of SEQ ID NO: 2.

Art Unit: 1638

The claims encompass nucleic acids that encode amino acid sequences that can differ from SEQ ID NO: 2 by as much as 10%. This corresponds to as many as 53 amino acids that can be changed to any other amino acid, save for the 17 amino acid sequence underlined in Figure 4. The specification does not teach any such sequences that still retain the function of SEQ ID NO: 2. No guidance is provided concerning the remainder of the residues that can be mutated without affecting functional activity. Applicants also argue that 90% sequence identity is a relatively narrow limitation compared with many granted patents having comparable disclosures (responses submitted June 11, 2003, paragraph bridging pages 4-5, and December 19, 2002, page 21, 3<sup>rd</sup> full paragraph). However, the claims encompass nucleic acids that encode amino acid sequences that can differ from SEQ ID NO: 2 by as much as 10%. This corresponds to as many as 53 amino acids that can be changed to any other amino acid, save for the 17 amino acid sequence underlined in Figure 4. This is not a simple narrow limitation. It is well known that a change in a single amino acid can change the activity of a polypeptide. The specification does not provide any guidance as to the amino acids that can be changed, and what they can be changed to, without affecting the functional activity of SEQ ID NO: 2. Further, that other patents may have limitations in claims that encompass broader limitations has no bearing on the instant application, as the inventions of each of those patents are independent and distinct from the instant invention. The claims in each of those patents were allowed based on entirely different fact patterns from those in the instant application.

Applicants argue that claim 59 has been amended to indicate that the host cell is a plant cell or bacterial cell (response submitted June 11, 2003, page 5, 2<sup>nd</sup> full paragraph). The claim amended overcomes this aspect of the rejection.

Art Unit: 1638

Applicants also argue that the Markush group claim 69 is enabled because the skilled person can use the invention to influence plant growth without significantly affecting flowering time, and cite two post-filing references in support (Xu et al., 2002, Poster abstract from the 10<sup>th</sup> International Plant Tissue Culture and Biotechnology Congress; Fu et al., Plant Cell, 2001, Vol. 13, pages 1791-1802; response submitted June 11, 2003, page 5, 3<sup>rd</sup> full paragraph to page 7, 1<sup>st</sup> full paragraph). However, the rejection did not raise this issue. Rather, the rejection raised the issue that the claim encompasses any kind of changes to plant growth and flowering time, whereas the specification only teaches that overexpression of GAI in transgenic plants would affect plant growth only by repressing it, and would only affect flowering time by delaying it.

## Summary

- 12. Claims 49-59 and 61-69 remain rejected.
- 13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1638

Page 10

however, will the statutory period for reply expire later than SIX MONTHS from the date of this

final action.

**Contact Information** 

Any inquiry concerning this or earlier communications from the examiner should be

directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can

normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy

Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this

application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular

communications and 703-872-9307 for After Final communications. Any inquiry of a general

nature or relating to the status of this application or proceeding should be directed to the

receptionist whose telephone number is 703-308-0196.

October 21, 2003

Ashwin D. Mehta, Ph.D.

Primary Examiner

Art Unit 1638